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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,702	09/13/2001	Edward A. Berger	4239-60771	9274

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EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,702

Applicant(s)

BERGER ET AL.

Examiner

Robert A. Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,23-33,37,48,52,53 and 56-69 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,23-33,37,48,52,53 and 56-69 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3-11-05.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

Art Unit: 1645

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 3-11-2005 has been entered.

The amendment filed on 3-11-2005 is acknowledged. Claims 61-69 have been added. Consequently, claims 1, 23-33, 37, 48, 52-54 and 56-69 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 3-11-2005 has been considered. An initialed copy is attached hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

Art Unit: 1645

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The aforementioned claims are drawn to kits comprising pharmaceutical compositions for the treatment and/or prevention of HIV infection. The specification however, is silent on how such a composition would be used and equally silent on the efficacy of said compositions. People of skill in the art require evidence that a benefit can be derived by the application of a given substance. The specification, as filed, does not set forth that the claimed compositions provide any sort of therapeutic or prophylactic effect in any model system that can be applied (or extrapolated) to humans or higher mammals (or in humans themselves). The specification describes discloses prophetic statements about possible applications including its use to “prevent” HIV infection before virus exposure (see page 27, lines 17-20). To date, there is no prophylaxis for HIV in man. It should be noted that the prophylactic use of the claimed fusion protein is encompassed by the instant claim. Moreover, since the specification is silent on how such a composition would be used and equally silent on the efficacy of said compositions it cannot be enabling for pharmaceutical compositions comprising the sCD4-SCFv(17b) bispecific fusion protein. Finally, while the skill in the art of immunology is high, to date, prediction of a therapeutic/protective benefit (effect) for any given composition is quite unpredictable. Moreover, while one may know how to make the composition (as is the case with sCD4-SCFv(12b)), no evidence has been provided that illustrates or even suggest that the claimed pharmaceutical compositions are capable of eliciting a beneficial or protective response, one of skill in the art has not been taught to use the claimed composition as a pharmaceutical, as is required by the claims.

Art Unit: 1645

Claims 1, 23-33, 48, 52-54, 61, 63-64 and 66-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the single-chain Fv SCFv(17b) is required in order to practice the claimed invention. The deposit of said biological materials is considered by the Examiner to be necessary for the enablement of the current invention (see 37 CFR 1.808(a)).

If the deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit, or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

- 1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- 2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent; and
- 3) the deposits will be maintained for a term of at least thirty (30) years from the date of the deposit or for the enforceable life of the patent or for a period of at least five (5) years after the most recent request for the furnishing of a sample of the deposited material, whichever is longest; and
- 4) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- 5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 – 1.809 for additional explanation of these requirements.

It should be noted that Applicant has previously argued that the amino acid and nucleic acid sequences of SCFv(17b) are provided in SEQ ID NO:3 and 4, respectively and hence a

Art Unit: 1645

deposit is not required. However, since the instant claims do not recite a single sequence setting forth the sequence of SCFv(17b), a deposit is required for the unique entity with the designation SCFv(17b).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 23-33, 37, 48, 52-24 and 56-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the language used to identify the second binding domain. Applicant recites that the second binding domain is SCFv(17b) indicating that the second binding domain is a single entity with a unique sequence. However, Applicant further claims that the second binding domain is encoded by an amino acid sequence comprising at least 90% sequence identity to residues 244 through 502 of SEQ ID NO:3 indicating that multiple sequences may be associated with the second binding domain. Since a unique entity (identified by the verb "is") cannot have multiple sequences, it is unclear what Applicant is attempting to claim. As such, it is impossible to determine the metes and bounds of the claimed invention.

Claims 52-54 are rendered vague and indefinite by being dependent on a canceled claim.

Conclusion

No claim is allowed.

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT A. ZEMAN
PATENT EXAMINER

September 12, 2005